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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/267,456	03/12/99	MOSCA	J 640100-295

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EXAMINER

EWOLDT, G

ART UNIT	PAPER NUMBER
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1644

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DATE MAILED:

07/05/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/267,456**

Applicant(s)  
**Mosca et al.**

Examiner  
**Gerald Ewoldt**

Group Art Unit  
**1644**



☒ Responsive to communication(s) filed on Jun 5, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-4 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-4 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

**DETAILED ACTION**

1. This application claims priority to U.S. provisional application Serial No. 60/080,678.
2. Applicant's election of Group I, Claims 1-4, in Paper No. 7, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 5-16 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.  
  
Claims 1-4 are being acted upon.
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:  
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 1-4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,962,320 in view of U.S. Patent No. 5,591,625.

The '320 patent teaches a method of inhibiting a T cell response to an antigen, including an autoimmune antigen, comprising contacting/administering to a subject cells, such as epithelial or muscle cells (column 9, paragraph 6), modified to present said antigen, thereby inhibiting a T cell response to said antigen (see particularly column 6, paragraph 8, and claim 11).

The '320 patent differs from the claimed invention in that it does not teach the use of mesenchymal stem cells as the modified antigen presenting cells for inhibiting an antigen specific T-cell response.

The '625 patent teaches the use of autologous modified mesenchymal stem cells transfected (modified) to express multiple genes of interest, including cell surface proteins such as antigens. Additionally, mesenchymal stem cells can be grown in bulk *in vitro* for reintroduction *in vivo* where they home to the bone marrow and can be manipulated to differentiate into any number of different cell types, including cells of the adipocyte lineage (see particularly columns 1-2).

From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use modified mesenchymal stem cells, as taught by the '625 patent, as antigen presenting cells in a method to inhibit a specific T-cell response, including a T cell response to an autoantigen, as taught by the '320 patent. One of ordinary skill in the art would have been motivated to use mesenchymal stem cells as the modified antigen presenting cells because of their versatility as evidenced by their advantageous growth characteristics and the fact that they can be manipulated to differentiate into specific cell types for direction into specific tissues, or home to the bone marrow for eventual differentiation into multiple cell types for dispersal into multiple tissues.

6. Claims 1-4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,747,299 in view of U.S. Patent No. 5,591,625.

The '299 patent teaches a method of inhibiting a T cell response to an antigen, including an autoimmune antigen, comprising contacting/administering to a subject cells, such as monocytes (column 3, paragraph 4), modified to present said antigen, thereby inhibiting a T cell response to said antigen (see particularly column 2 last paragraph - column 3 first paragraph, and column 7 last paragraph - column 8 first paragraph).

The '299 patent differs from the claimed invention in that it does not teach the use of mesenchymal stem cells as the modified antigen presenting cells for inhibiting an antigen specific T-cell response.

The '625 patent teaches the use of autologous modified mesenchymal stem cells transfected (modified) to express multiple genes of interest, including cell surface proteins such as antigens. Additionally, mesenchymal stem cells can be grown in bulk *in vitro* for reintroduction *in vivo* where they home to the bone marrow and can be manipulated to differentiate into any number of different cell types, including cells of the adipocyte lineage (see particularly columns 1-2).

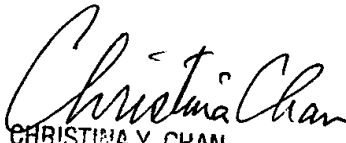
From the teachings of the references it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use modified mesenchymal stem cells, as taught by the '625 patent, as antigen presenting cells in a method to inhibit a specific T-cell response, including a T cell response to an autoantigen, as taught by the '299 patent. One of ordinary skill in the art would have been motivated to use mesenchymal stem cells as the modified antigen presenting cells because of their versatility as evidenced by their advantageous growth characteristics and the fact that they can be manipulated to differentiate into specific cell types for direction into specific tissues, or home to the bone marrow for eventual differentiation into multiple cell types for dispersal into multiple tissues.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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June 30, 2000

  
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